IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND, on behalf of itself and all others similarly situated, JOSEPH MACKEN, and COMMISSIONER LINDA A. WATTERS	)	
Plaintiffs,	)	
v.	)	Civ. No. 05-075-SLR (Lead Case)
ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, LP,	)	
Defendants.	)	

DEFENDANTS' OPENING BRIEF
IN SUPPORT OF THEIR MOTION TO DISMISS

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MISCELLANEOUS

Defendants AstraZeneca Pharmaceuticals LP and Zeneca Inc. (collectively "AstraZeneca") respectfully submit this Brief in support of their Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint ("Complaint" or "Compl."), pursuant to Federal Rules of Civil Procedure 9(b), 12(b)(1) and 12(b)(6), for lack of standing and failure to state a claim upon which relief can be granted.

NATURE AND STAGE OF THE PROCEEDING

On February 11, 2005, Pennsylvania Employee Benefit Trust Fund ("PEBTF") filed a putative nationwide class action. *Pennsylvania Employee Benefit Trust Fund v. Zeneca, Inc., et al,* Case No. 05-00075-SLR ("PEBTF Action") (D.I. 1).[1] On April 5, 2005, Linda A. Watters, Commissioner, Offices of Financial Services for the State of Michigan ("Watters") in her capacity as Rehabilitator of The Wellness Plan ("Wellness Plan") and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc. ("OmniCare") filed a putative nationwide class action. *Watters v. AstraZeneca Pharmaceuticals LP, et al.,* Case No. 05-00196-SLR ("Watters Action") (D.I. 1). On April 14, 2005, Joseph Macken ("Macken") filed a putative nationwide class action. *Macken v. AstraZeneca Pharmaceuticals LP, et al.,* Case No. 05-00220 ("Macken Action") (D.I. 1).

Pursuant to this Court's June 23, 2005 Pretrial Order No. 1 (D.I. 27): (1) the *PEBTF*, *Watters*, and *Macken* Actions were consolidated; and (2) on May 27, 2005, PEBTF, Watters, and Macken, along with AFSCME District Council 47 Health & Welfare Fund ("AFSCME"), Victoria Scofield ("Scofield"), Janet McGrorty ("McGrorty"), Richard Tikkuri ("Tikkuri"), Wisconsin Citizen Action ("WCA"), United Senior Action of Indiana ("USAI"), and North

[1] Unless otherwise noted, all references to "D.I." are to docket items in the *PEBTF* Action.

Carolina Fair Share ("NCFS") (collectively, "Plaintiffs") filed a putative nationwide class action (D.I. 20).[2]

Plaintiffs contend that AstraZeneca deceived the United States Food and Drug Administration ("FDA"), physicians, and consumers about the relative merits of NEXIUM® (esomeprazole magnesium) and PRILOSEC® (omeprazole) and thereby created demand for Nexium that otherwise would not exist. *E.g.*, Compl. ¶ 135. Plaintiffs assert that AstraZeneca gained FDA approval for Nexium by submitting "skewed" and "slanted" studies that compared "essentially non-equivalent doses" of Prilosec and Nexium. *Id.* ¶¶ 11, 73, 75, 135. Plaintiffs then assert that AstraZeneca conducted a massive advertising campaign that misleadingly failed to disclose that "double the standard dose of Prilosec" is "equally as effective" as Nexium. *Id.* ¶¶ 77, 86-104, 133, 135, 137, 139, 141, 143, 145.

Plaintiffs seek to represent a nationwide class of disparate Nexium purchasers, including "consumer[s], third party payors, cash payors and those making a co-pay." *Id.* ¶ 147.[3] Plaintiffs allege four causes of action: (1) violation of the Delaware Consumer Fraud Act, 6 Del. Code § 2511 *et seq.* ("DCFA") (*id.* ¶¶ 154-64; (2) violations of "the Consumer Protection Statutes of the 50 States" (*id.* ¶¶ 165-72); (3) unjust enrichment (*id.* ¶¶ 173-78); and (4) negligent misrepresentation (*id.* ¶¶ 179-84). Plaintiffs seek actual damages, punitive damages, restitution, disgorgement, injunctive relief, pre-judgment interest, post-judgment interest, costs of suit, and attorneys' fees. *Id.* Prayer ¶¶ B-G.

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[2] Plaintiffs exclude from the putative class "persons or entities whose purchase [of Nexium] was made in the Commonwealth of Massachusetts or the State of California." *Id.* ¶ 147.

[3] This brief refers to Macken, McGrorty, Scofield, and Tikkuri as "Individual Plaintiffs"; to PEBTF, AFSCME, and Watters (on behalf of Wellness Plan and OmniCare) as "Third Party Payor Plaintiffs"; and to WCA, USAI, and NCFS as "Associational Plaintiffs."

SUMMARY OF ARGUMENT

1. Plaintiffs invoke state law to challenge all of AstraZeneca's advertising for Nexium. They contend that every ad for Nexium inherently implicitly conveys the message that Nexium is superior to Prilosec, and that this message is false and misleading. Plaintiffs therefore argue that AstraZeneca either should not market Nexium at all, or should disclose in its ads that "Nexium is not superior to Prilosec in any fashion," that AstraZeneca "manufactures a far less expensive drug that is equally as effective" as Nexium, that "virtually the exact same product can be bought from the same manufacturer at a lower price and that the lower priced product can achieve the same clinical benefits," and the like. *E.g.*, Compl. ¶¶ 131, 140, 155(b).

2. Plaintiffs' Complaint should be dismissed with prejudice for three basic reasons: (1) it raises claims that are within a safe harbor under state law, or are preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and by regulations promulgated by the FDA, or both; (2) the claims are barred by the First Amendment, which protects the commercial speech challenged here as a matter of law; (3) it lacks allegations sufficient to demonstrate injury-in-fact or causation under Article III and standing under state law.

3. Plaintiffs' attack on the fact of advertising and all advertising per se of an FDA-approved drug is unprecedented and unsupportable. To the extent the Complaint states any claim otherwise viable under state law, it is preempted, for two reasons. First, Plaintiffs do not allege that the advertising statements they challenge are inconsistent with the FDA-approved labeling for Nexium. They cannot do so. Under their theory, the same implicit message of superiority that allegedly flows from AstraZeneca's advertising also flows, necessarily, from the FDA-approved labeling for Nexium. Advertisements that "comport substantively," even if not "precisely," with the FDA-approved labeling are not actionable. *Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998).

4. Second, federal law prohibits manufacturers from making the disclosures of "equal efficacy" that Plaintiffs seek to compel AstraZeneca to make here. Plaintiffs concede that, at the maximum doses approved by the FDA, Nexium is "more effective" than Prilosec at healing erosive esophagitis. Compl. ¶¶ 50, 54, 58. Plaintiffs nevertheless argue that Nexium is a related compound to Prilosec, and predict that "double the standard dose [20 mg] of Prilosec" would be equally as effective as 40 mg of Nexium. *Id.* ¶ 77. The FDA bars pharmaceutical companies, however, from "recommending or suggesting" a non-approved dosing regimen. 21 C.F.R. § 202.1(e)(4)(i)(a); *see also* 21 U.S.C. § 301 *et seq*. Not only has the FDA not approved a 40 mg dose of Prilosec for healing erosive esophagitis, the Prilosec labeling expressly states that a 40 mg dose of Prilosec has not been demonstrated to be more effective than a 20 mg dose of Prilosec. Because federal law bars promotion of non-approved dosing regimens, state law may not condition the marketing of Nexium on any disclosure related to a "double-dose" of Prilosec. *E.g., Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 941-43 (7th Cir. 2001) (affirming dismissal of a "double-dose" class-action complaint against the manufacturer of Zantac).

5. Plaintiffs' claims are independently barred by the First Amendment. First, the *Noerr-Pennington* doctrine absolutely protects AstraZeneca's decision to seek approval for a 40 mg dose of Nexium, and hence to market Nexium based upon that approval. Second, because Plaintiffs seek to challenge only an implicit message of superiority, they have failed to allege facts sufficient to demonstrate that AstraZeneca's advertising of Nexium is "inherently misleading" as a matter of law. The challenged advertising is therefore commercial speech subject to constitutional protection, and the Complaint lacks any allegations that would enable the requested restrictions on speech to survive strict or even intermediate scrutiny. Third,

Plaintiffs' proposed disclosure requirement, if imposed by state law, would constitute impermissible compelled speech.

6. Finally, Plaintiffs lack standing under Article III and state law to bring these claims. Plaintiffs have failed to allege injury-in-fact or causation because none has alleged (a) that they saw any Nexium advertisement; (b) how a Nexium advertisement affected their decision to purchase, or reimburse for, Nexium; or (c) what drug they would have purchased, or provided reimbursement for, instead of Nexium and at what cost. Their failure to plead any of the rudiments of a true false advertising claim is revealing. It confirms that this case is not really about false advertising. Rather, Plaintiffs have borrowed the mantle of false advertising to cloak what is really a claim that the approval and marketing of Nexium is per se unlawful.

7. This Complaint should be dismissed with prejudice. Plaintiffs seek to debate whether it is unfair for a pharmaceutical company to introduce and market a new drug after FDA approval that Plaintiffs contend is neither cheaper nor more effective than its existing drug. Federal and state courts are not the place for that debate. Such an argument must be directed, if anywhere, to the FDA or to Congress.

STATEMENT OF FACTS

A. Regulatory Background

Nexium, like all prescription drugs, is subject to extensive regulation by the FDA. The approval of a new drug, the adequacy of supporting clinical studies, the appropriate dosages of a new drug, the labeling for the drug, its formulation and color, and the promotion of prescription drugs in a manner consistent with that labeling are all issues that Congress has committed exclusively to the FDA. 21 U.S.C. § 301 *et seq.*

1. New Drug Approval

The FDA has exclusive jurisdiction to determine whether to approve a "new drug application" ("NDA") to market a drug in the United States. 21 U.S.C. §§ 355(a), (b). Among other things, the NDA must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b). The NDA also must include a copy of the proposed labeling for the drug. *Id.*; 21 C.F.R. § 314.50(c)(2)(i). The FDA will approve an NDA only "after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." *Id.* § 314.105(c); 21 U.S.C. § 355(b).

Plaintiffs acknowledge that AstraZeneca received regulatory approval from the FDA to market Nexium. Compl. ¶ 6. Results of clinical studies that were submitted to the FDA as part of the Nexium NDA are reflected in the FDA-approved Nexium labeling (also known as a "package insert"), which Plaintiffs quote in their Complaint. *Id.* ¶ 75.[4] The labeling contains the approved uses (or "indications"), as well as the FDA-approved doses, for the drug. *See* 21 C.F.R. § 201.57(c), (j).

2. Determining The Propriety And Adequacy Of Clinical Studies

FDA approval of a new drug also includes a determination that the clinical studies submitted to support such approval meet the statutory standards of being "adequate and well-controlled." *See* 21 U.S.C. § 355; 21 C.F.R. § 314.126. The FDA will deny an NDA if it determines that there "is a lack of substantial evidence consisting of adequate and well-

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[4] For the Court's convenience, complete copies of the FDA-approved Nexium, Prilosec, and Prilosec OTC labeling are attached as Exhibits 1, 2, and 3 to the concurrently filed Request for Judicial Notice ("RJN"). This Court may consider this labeling in ruling on this Motion. *See* RJN; *see also Bober*, 246 F.3d at 940-43.

controlled investigations" that the drug is effective under the conditions, including at the dosage, prescribed, recommended, or suggested in its labeling. 21 C.F.R. § 314.125(b)(5); *see also* 21 U.S.C. §§ 355(d), 352(f)(1); 21 C.F.R. § 201.100(d). The FDA's decision to include the results of a clinical study in the labeling reflects a determination by the FDA not only that the study was "adequate and well-controlled,"[5] but also that the information in the labeling is not "false or misleading," *see id.* § 314.125(b)(6) (FDA must deny an NDA if it determines that "[t]he proposed labeling is false or misleading in any particular"). The FDA has the authority to detect and punish fraud in connection with petitions to the agency. *See generally Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001).

3. Prescription Drug Advertising

The FDA is responsible not only for approving prescription drugs for marketing and distribution in the United States, but also for regulating promotional materials. *See* 21 U.S.C. § 352(n); *see also id.* §§ 321(n), 331(a), 352(a). This latter function is performed by the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC"). The Federal Trade Commission ("FTC") agrees that the FDA should exercise primary responsibility for regulating advertising of prescription drugs. *Working Agreement Between FTC and Food and Drug Administration*, 4 Trade Reg. Rep. (CCH) ¶ 9851 (1971) ("*Working Agreement*").

Once the FDA has approved a new drug, the manufacturer has the right to market the drug in accordance with the FDA-approved labeling. *See, e.g.*, 21 C.F.R. § 202.1(e)(4)(i)(a). The FDA requires the manufacturer to submit promotional labeling and advertising for the drug

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[5] *See* FDA, *Guidance for Industry: Clinical Studies Section of Labeling for Prescription Drugs and Biologics – Content and Format* (July 2001) (DRAFT), *available at* www.fda.gov/cder/guidance/1890dft.htm (last visited June 30, 2005) (studies that are not adequate and well-controlled should usually not be included in the Clinical Studies section of the labeling); *see also* 21 C.F.R. § 201.57(m).

to DDMAC at the time of first use. 21 C.F.R. § 314.81(b)(3)(i). The FDA permits, and in some cases requires, manufacturers to submit their ads to DDMAC for advance approval. 21 C.F.R. § 202.1(j). The FDA has numerous options for addressing advertising that does not comply with the agency's detailed regulatory requirements. *See* 21 U.S.C. § 332 *et seq.* (seizure, injunction, criminal fines, imprisonment); *cf. United States v. Park*, 421 U.S. 658 (1975) (strict criminal liability of CEO for violations of the FDCA).

Since 1985, the FDA has permitted drug manufacturers to promote prescription drugs not only to physicians but also directly to consumers ("DTC" advertising). *See generally* 60 Fed. Reg. 42,581, 42,581-82 (Aug. 16, 1995) (discussing history of DTC advertising); *see also* 21 C.F.R. § 202.1 (advertising regulations). The FDA frequently reviews broadcast DTC advertisements prior to their use. *See* 60 Fed. Reg. 42,581, 42,581-82 (Aug. 16, 1995); Statement of Janet Woodcock, M.D., before the Sen. Special Comm. on Aging, July 22, 2003, *available at* http://www.hhs.gov/asl/testify/t030722b.html (last visited June 30, 2005).

B. Summary Of Plaintiffs' Allegations

Plaintiffs contend that AstraZeneca engaged in a "multi-prong attack" to switch consumers from Prilosec to Nexium. Compl. ¶ 6. First, Plaintiffs allege that AstraZeneca "hauled generic manufacturers into court seeking to delay entry of competition." *Id.* ¶ 6. AstraZeneca then sought and "received FDA approval for a new PPI, Nexium," *id.* ¶ 6, which Plaintiffs contend is "virtually the exact same" as Prilosec. *Id.* ¶ 155(b); *see also id.* ¶ 9. Finally, Plaintiffs allege that AstraZeneca conducted a "[m]assive [p]romotional [c]ampaign . . . to [e]stablish Nexium as a [s]ubstitute for Prilosec." *Id.* at 20; *see also id.* ¶¶ 86-104.

Plaintiffs allege that clinical studies comparing Prilosec and Nexium were "crucial to AstraZeneca's marketing strategy" (*id.* ¶ 10), and that the studies were not "fair and objective," but "skewed and "slanted." *Id.* ¶¶ 11, 75, 135. Plaintiffs repeatedly fault AstraZeneca for

comparing "essentially non-equivalent doses" of Nexium (*i.e.*, 40 mg and 20 mg) to the "standard 20 mg dose of Prilosec." *Id.* ¶¶ 73, 75-80. Plaintiffs acknowledge, however, that the studies about which they complain were submitted to the FDA as part of the Nexium NDA, that the FDA reviewed the studies and based its approval of Nexium at least in part upon them. *Id.* ¶ 49, *see also id.* ¶¶ 10, 48-69. The results of these studies appear on the FDA-approved Nexium labeling, which Plaintiffs quote in the Complaint. *Id.* ¶ 75; *see also* Nexium Labeling, at 13-14 (RJN, Ex. 1).[6] Yet in Plaintiffs' judgment, the clinical studies do not support the use of Nexium. Compl. ¶ 74; *see also id.* ¶¶ 51-52. Plaintiffs allege that the "objective conclusion" from these studies would have been to "double the standard dose of Prilosec, allow generic competition, sell Prilosec over-the-counter, and forget about [Nexium]." *Id.* ¶¶ 75-77; *see also id.* ¶ 11.

Plaintiffs specifically challenge AstraZeneca's application for, and the FDA's approval of, a 40 mg dose of Nexium for healing erosive esophagitis. *E.g.*, *Id.* ¶ 155(e). For example, Plaintiffs quote an "FDA reviewer" as stating: "'For this indication, as with the previous two, there is no benefit when increasing the H [Nexium] dose from 20 to 40 mg. Thus the recommended dose of Nexium is 20 mg once-a-day." *Id.* ¶ 79. Plaintiffs nevertheless cannot dispute that the FDA-approved Nexium labeling, which they quote in their Complaint, includes (a) a 40 mg dose of Nexium for healing erosive esophagitis, and (b) summaries of two studies showing that a 40 mg dose of Nexium is more effective than either a 20 mg dose of Nexium or a 20 mg dose of Prilosec. *See id.* ¶¶ 75, 80; *see also* Nexium Labeling, at 13-15, 37 (RJN, Ex. 1).

Plaintiffs also contend that AstraZeneca's marketing of Nexium was misleading because it implicitly promoted Nexium to physicians and consumers as more effective than Prilosec.

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[6] The original complaints that Plaintiffs Watters and Macken filed reproduced the charts contained in the Nexium labeling that summarize the results of these studies. *See Watters* (continued . . .)

Compl. ¶¶ 7, 12, 78, 87-98, 100, 155(c), 155(f), 155(i), 155(j), 155(k), 155(o). Plaintiffs purport to quote four television ads and to attach twelve print ads to their Complaint. *Id.* ¶¶ 112-13, 115, 118, 123-24, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144. Only two of the television ads and six of the print ads use the word "Prilosec," and none expressly states that Nexium is more effective than Prilosec. *Id.* ¶¶ 112-13, 123-24, 126, 128, 130, 134. Indeed, Plaintiffs allege that "[b]y 2002, all references to Prilosec were deleted from Nexium television advertisements." *Id.* ¶ 122. Plaintiffs nonetheless contend that all of these ads are misleading because they convey an implicit message that Nexium is superior to Prilosec (*id.* ¶¶ 92-93, 114, 116-17, 122, 125, 127, 129, 131, 133, 135, 139, 141, 145), while "fail[ing] to disclose that . . . AstraZeneca manufactures a far less expensive drug [Prilosec] that is equally as effective." *Id.* ¶ 133; *see also id.* ¶¶ 92, 94, 114, 121-22, 125, 127, 129, 131, 133, 135, 137, 139, 141, 143, 145, 155(b), 155(c), 155(k), 155(n). For example, here is the first television advertisement that Plaintiffs cite:

> I'm every man. And every woman who ever suffered from frequent, persistent heartburn. If you've treated your heartburn and changed your diet, but the pain comes back two or more days a week, then you may think you know about acid reflux disease. But there's something about acid reflux that I didn't know. Over time, that acid churning up can wear away the lining of your esophagus. I didn't know. I didn't know. I didn't know. Just one prescription Nexium a day gives many people complete resolution of heartburn symptoms. That could mean complete heartburn relief. And Nexium is also proven to heal erosions in the esophagus caused by acid reflux. Only a doctor can determine if you have this damage. Other serious stomach conditions may still exist. ***The most common side effects of Nexium and Prilosec*** are headache, diarrhea and abdominal pain. So talk to your doctor, and call this number for more information and for a free trial certificate for Nexium. ***Relieve the heartburn, heal the damage. It's possible with the new purple pill called Nexium.*** [Emphasis in Complaint]

(. . . continued)

Class Action Complaint, ¶¶ 80, 82; *Macken* Class Action Complaint, ¶¶ 41, 43.

Id. ¶ 112. Plaintiffs allege that this ad is "deceptive, unfair and misleading as [it] intended to and did create the impression that the 'new purple pill' was an improvement over the 'purple pill' that had previously been available, namely Prilosec." *Id.* ¶ 114.

ARGUMENT

A complaint should be dismissed under Federal Rule of Civil Procedure 12(b)(6) where, "even accepting the allegations in the complaint as true and drawing every reasonable inference in favor of the plaintiffs, they have failed to adequately plead . . . [a] cause of action." *Lum v. Bank of Am.*, 361 F.3d 217, 223 (3d Cir. 2004); *see also* Fed. R. Civ. P. 12(b)(6). "But a court need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss." *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906, 906 n.8 (3d Cir. 1997) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1429-30 (3d Cir. 1997)).

This Complaint should be dismissed for three reasons. First, Plaintiffs' attack on the marketing of an FDA-approved medication is preempted. Second, Plaintiffs' claims are barred by the First Amendment. Third, Plaintiffs lack standing under Article III and state law.

I. PLAINTIFFS' FALSE ADVERTISING CLAIMS ARE PREEMPTED

This lengthy Complaint presents, in essence, a single contention. Plaintiffs contend that every Nexium ad inherently conveys the message that Nexium is superior to Prilosec. The ads are misleading and unlawful, Plaintiffs argue, because they do not contain an express disclaimer that Nexium is not cheaper or more effective than Prilosec.

Specifically, Plaintiffs claim that every Nexium ad inherently implies superiority. Compl. ¶¶ 7, 125, 133, 135, 137, 139, 141, 143, 145, 155(f), 155(i), 155(j), 155(k). This inference allegedly is inherent in the Defendants' decision to market Nexium. *Id.* ¶¶ 127, 129, 131, 155(o). It allegedly is inherent in the description of Nexium as "new," *id.* ¶¶ 114, 116, 122, 125, 127, in the very color of the Nexium capsule, *id.* ¶¶ 114, 116-17, 122, 133, 139, 141, 145,

155(f), and in the statement of the indications for which Nexium has been approved, *id.* ¶ 135, 137. It allegedly flows from Nexium ads that mention Prilosec, *id.* ¶¶ 112-13, 116, 123-31, 134-35, and those that do not. *Id.* ¶¶ 115-18, 132-33, 136-45. The inference even allegedly flows from the suggestion that patients "talk to their doctor" about Nexium. *Id.* ¶¶ 120, 121.

Plaintiffs then argue that, given this pervasively implicit message, AstraZeneca was required either to abandon any marketing of Nexium (*id.* ¶¶ 155(n), 163), or to disclose in each ad "that AstraZeneca manufactures a far less expensive drug that is equally as effective [as Nexium]," *id.*, or provide a similar "disclos[ure]" that Nexium offers "no benefit over" Prilosec. *Id.* ¶¶ 121-22; *see id.* ¶¶ 92, 94, 96-97, 114, 131, 121-22, 125, 127, 129, 143, 145, 155(b), 155(c), 155(n) (similar challenge to each print and broadcast ad); *see also id.* ¶¶ 88-90, 92-93, 94 (similarly attacking AstraZeneca for it allegedly failed to tell doctors – viz., that "[n]o mention was made in this advertisement or in any of the promotional materials distributed by the AstraZeneca sales force that in equivalent doses, Nexium was not more effective or powerful tha[n] Prilosec"); *see also id.* ¶¶ 125, 127, 135, 137, 143, 145.[7]

Plaintiffs' claim is preempted by federal law for two fundamental reasons.[8] First, none of the advertising that Plaintiffs challenge is inconsistent with the FDA-approved Nexium labeling.

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[7] The only even arguably affirmative statements of "superiority" to which Plaintiffs have pointed appear in AstraZeneca's Annual Report for the year 2000. *Id.* ¶ 89. Although Plaintiffs contend that the 2000 Annual Report contains "themes" of superiority that appear in subsequent advertisements, their examples do not support that contention. Plaintiffs also do not contend that the 2000 Annual Report itself is an advertisement, or that the 2000 Annual Report was ever seen by or caused injury to any Plaintiff. The Annual Report alone cannot support a claim of false advertising. In any event, as shown below, the statements in the 2000 Annual Report are fully consistent with the labeling that the FDA ultimately approved.

[8] State laws that interfere with or are contrary to federal law are preempted. U.S. Const., art. VI, cl. 2; *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873 (2000). State law is preempted where "Congress has intended, by legislating comprehensively, to occupy (continued . . .)

Indeed, Plaintiffs do not, and cannot, make any such claim. They concede that the same implicit message of superiority that they claim to find in AstraZeneca's advertising is also present in the labeling itself. Advertising statements that are consistent with FDA-approved labeling may not be challenged as misleading under state law.

Second, the disclosures that Plaintiffs seek to impose under state law are ones that the FDA bars a manufacturer from making under federal law. Plaintiffs' case for the alleged equivalence of Nexium and Prilosec depends – concededly and crucially – on their assertion that a double dose of Prilosec is as effective as a single 40 mg dose of Nexium. The FDA bars manufacturers from promoting off-label dosages of any drug. The disclosure that Plaintiffs seek, therefore, is one that AstraZeneca is not permitted to make.

A. Plaintiffs' "Implicit Message" Theory Conflicts With Federal Law

Plaintiffs contend that every Nexium advertisement, whether it mentions Prilosec or not, implicitly conveys a message that Nexium is better than Prilosec. Even assuming Plaintiffs could prove that contention (and given the nature of the ads they quote, that is a stretch in itself), the contention is unavailing. Plaintiffs do not allege, and cannot allege, that this implicit message is outside the bounds of what the FDA-approved Nexium labeling permits. To the contrary, the FDA-approved Nexium labeling conveys the very same message. Compl. ¶¶ 48-51, 54, 58. Claims under state law that this implicit message is misleading are thus preempted.

(. . . continued)

an entire field of regulation and has thereby 'left no room for the States to supplement' federal law" (*Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699 (1984) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)), and when it "conflicts with federal law or 'stands as an obstacle to the accomplishment of the full purposes and objectives of Congress.'" *Lawrence County v. Lead-Deadwood Sch. Dist. No. 40-1*, 469 U.S. 256, 260 (1985) (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984)).

First, Plaintiffs concede (and the Nexium labeling confirms) that the FDA approved a maximum daily dosage of 40 mg Nexium for healing erosive esophagitis. *See id.* ¶¶ 6, 80; *see also* Nexium Labeling, at 37 (RJN, Ex. 1). Plaintiffs further admit that two studies summarized on the Nexium labeling show that the 40 mg dose of Nexium has a "higher healing" rate and is "more effective" than the maximum approved dose of Prilosec for healing erosive esophagitis, which is 20 mg daily. Compl. ¶¶ 50, 54, 58. Plaintiffs state:

- "Study 172 compared the efficacy of Nexium 40 mg, Nexium 20 mg, Nexium, and omeprazole 20 mg [Prilosec] in healing erosive esophagitis. . . . Not surprisingly, Nexium 40 mg had a statistically significant higher healing proportion than omeprazole 20 mg, 87.6% versus 81.4%." (*Id.* ¶ 50).[9]

- "AstraZeneca attempted yet again to prove that 40 mg of Nexium was better at healing erosive esophagitis than 20 mg of omeprazole in Study 222. . . . With this lower measure of therapeutic gain, AstraZeneca was finally able to show, within the parameters of the study, that 40 mg of Nexium was more effective than 20 mg of omeprazole. (*Id.* ¶ 58)."

These admissions foreclose Plaintiffs' attack on any implied message of greater effectiveness. They demonstrate that any such implicit message is consistent with the Nexium labeling.

Plaintiffs concede the superiority of Nexium to Prilosec at the approved doses of each in yet a second respect. They argue that the "objective conclusion" from AstraZeneca's research on the effectiveness of Nexium would be to "double the standard dose of Prilosec" and to "forget about" marketing Nexium. *Id.* ¶ 77. Plaintiffs thus concede that it would not be "objective" for a physician who wanted to obtain efficacy comparable to Nexium to continue to prescribe only a single dose of Prilosec. Rather, to achieve efficacy equivalent to Nexium using Prilosec, Plaintiffs contend that a physician must double the FDA-approved dose of Prilosec. *See also id.*

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[9] Throughout this memorandum, all emphases are added unless otherwise noted.

¶¶ 52, 94. For this reason as well, the implicit message of greater efficacy that Plaintiffs contend is in AstraZeneca's ads is also concededly present in the Nexium labeling.

Third, even apart from these concessions, the implicit message of superiority that Plaintiffs seek to condemn in AstraZeneca's advertising is also present in the Nexium labeling itself. The labeling (which Plaintiffs quote and hence effectively incorporate into their Complaint) includes two charts summarizing studies of patients with erosive esophagitis that compare Nexium and Prilosec. *See id.* ¶ 75; *see also* Nexium Labeling, at 13-14 (RJN, Ex. 1).

The first chart summarizes healing rates in four studies for patients with erosive esophagitis; it shows (among other things) that in two studies (studies 2 and 4), "NEXIUM 40 mg" demonstrated statistically significant and higher healing rates for erosive esophagitis than did "Omeprazole [Prilosec] 20 mg." *Id.* at 13. The second chart summarizes resolution of heartburn symptoms for patients with erosive esophagitis; it similarly shows that in two studies (again studies 2 and 4), Nexium 40 mg demonstrated statistically significant and higher percentages of sustained resolution of heartburn than did omeprazole (Prilosec) 20 mg. *Id.* at 14.

These charts thus summarize data showing that the maximum-approved daily dose of Nexium (40 mg) provides statistically significant higher healing and symptom-resolution rates for patients with erosive esophagitis than does the maximum approved daily dose of Prilosec (20 mg). Compl. ¶¶ 50, 54, 58. The labeling also states the approval of a 40 mg dose of Nexium for treating erosive esophagitis. If any message of greater effectiveness flows implicitly from AstraZeneca's ads, it also necessarily is conveyed by the FDA-approved Nexium labeling itself.

Because AstraZeneca's advertising is consistent with its FDA-approved labeling, it complies with federal law.[10] The advertising is therefore not actionable under Delaware law.[11] Although the DCFA bars false advertising (see 6 Del. Code § 2513(a)), the DCFA excludes "any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission." 6 Del. Code § 2513(b)(2). As noted above, the FTC enforces the FDCA through its *Working Agreement* with the FDA. Accordingly, for purposes of the DCFA exclusion in the case of prescription drugs, the Court must look to FDA rules and regulations. *See, e.g., American Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D. N.Y. 1987) (applying New York analog to Section 2513(b)(2) and holding that "compliance with FDA labeling standards automatically puts it in compliance with FTC requirements as well, since the FTC has officially recognized that the FDA has primary jurisdiction over all matters relating to the labeling of OTC drugs"). Because Plaintiffs have not alleged, and cannot allege, any factual basis for claiming that the allegedly implicit message of superiority in AstraZeneca's ads is inconsistent with the Nexium labeling as approved by the FDA, Plaintiffs' claims are precluded under Delaware law. *See Bober*, 246 F.3d at 941-43 (construing safe harbor in Illinois Consumer Fraud Act).

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[10] Congress and the FDA have established detailed regulations governing the labeling of prescription drugs and those regulations define the scope of representations that may or may not be made by a prescription drug manufacturer. Under the FDCA and applicable FDA regulations, a prescription drug's label must be approved by the FDA before the drug can be sold. *See* 21 U.S.C. §§ 352, 355(b)-(e); 21 C.F.R. §§ 314.50(c)(2)(i); 314.105(c), 314.125; *see also* 21 C.F.R. § 201.57.

[11] Plaintiffs' "[a]lternative[]" claim for violation of the deceptive practices and consumer fraud acts of the fifty states (Compl. ¶ 166), should be dismissed because the arguments for preemption apply equally to any state law, and because "shotgun" pleading of violations of the consumer fraud laws of fifty states is "overinclusive" and disregarded on a motion to dismiss. *See, e.g., Fitzgerald v. Chrysler Corp., 1996 WL 473456*, at *7 (N.D. Ill. 1996), *aff'd*, 116 F.3d 225 (7th Cir. 1997).

Even if Delaware law could be construed to bar advertising that was consistent with FDA-approved labeling, that law would be preempted. State laws that would brand as "deceptive" the marketing of FDA-approved drugs in a manner consistent with their FDA-approved labeling would chill the promotion of prescription medication, frustrate Congress's purpose in granting the FDA exclusive authority to determine whether to approve a new drug for marketing in the United States, and conflict with the FDA's necessary finding, in approving the labeling, that the labeling is not "false or misleading." *See* 21 U.S.C. §§ 355(b)-(d); 21 C.F.R. §§ 201.56(b), 314.105(c), 314.125(b)(6); *see Buckman*, 531 U.S. at 349-51 (Congress did not intend state tort law to interfere with the FDA's administration of the food and drug laws).

For example, in *Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998), the district court granted defendant's motion to dismiss to the extent that challenged statements "comport substantively," even if not "precisely," with the FDA-approved labeling. The court explained that "[w]hatever the merits of NSI's contentions regarding purported deficiencies in the testing and development of ThinPrep, representations by Cytyc that comport substantively with statements approved as accurate by the FDA cannot supply the basis for NSI's claims." *Id.* The court therefore held that, "[a]lthough Cytyc's statements do not correspond precisely to statements that the FDA has approved, the challenged statements discussed above are similar enough to the approved statements for the Court to conclude, as a matter of law, that they are neither false nor misleading." *Id; see also SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 1996 WL 280810, at *13 (S.D.N.Y. 1996) (in a Lanham Act case, holding that the advertisements in question were "neither facially false nor misleading" because "[e]ach of the claims . . . challenge[d wa]s based on the package labelling approved by the FDA"); *Kanter v. Warner-*

Lambert Co., 99 Cal. App. 4th 780, 795-96 (2002) (holding that false advertising claim based on advertisement that repeated information in FDA-approved labeling was preempted by federal law); *American Home Prods.*, 672 F. Supp. at 144 (holding that "compliance with FDA warning requirements" is a complete defense to Lanham Act and unfair competition claims).[12]

In sum, Plaintiffs cannot allege that AstraZeneca's advertising is inconsistent with its FDA-approved labeling. Plaintiffs' attack on the implied message of superiority to Prilosec is therefore preempted. The FDA approved a 40 mg dose of Nexium and approved labeling that compares Nexium to Prilosec and that summarizes the clinical studies that Plaintiffs now dispute. The FDA therefore authorized AstraZeneca to bring Nexium on to the market as a new PPI and to advertise consistent with this approval.[13] Advertising consistent with the FDA's approval of Nexium and its labeling is therefore barred from attack under state law.

B. Plaintiffs' Non-Disclosure Theory Also Conflicts With Federal Law

There is a second reason why Plaintiffs' false advertising claims are preempted. Plaintiffs assert that AstraZeneca could have lawfully marketed Nexium, but only if its ads included a disclosure that "double the standard dose" of Prilosec would be "equally as effective"

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12 The Federal Insecticide, Fungicide, and Rodenticide Act similarly preempts false advertising claims where the advertising is consistent with EPA-approved labeling. *See Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993); *Papas v. Upjohn Co.*, 985 F.2d 516, 519 (11th Cir. 1993); *Mortellite v. Novartis Corp. Prot., Inc.*, 278 F. Supp. 2d 390, 400-01 (D.N.J. 2003); *Sowers v. Johnson & Johnson Med., Inc.*, 867 F. Supp. 306, 313 (E.D. Pa. 1994).

13 Indeed, FDA guidance expressly permits manufacturers to describe newly approved drugs as "new" for the six months after their launch. *See* FDA DDMAC Frequently Asked Questions, *available at* http://www.fda.gov/cder/ddmac/FAQS.HTM#new (last visited June 30, 2005); 3 Trade Reg. Rep. (CCH) ¶ 7765 n.20 (citing FTC Advisory Opinion #120).

as a 40 mg dose of Nexium in healing erosive esophagitis, and "far less expensive" than Nexium. *E.g.*, Compl. ¶¶ 77, 133, 135, 137, 139, 141, 143, 145. For example:

> • "Even if duration of suppression of gastric acid secretion were a valid measure upon which to make a clinical decision, these results show that a single dose of Nexium 40 mg (keeping gastric pH above 4 for 14 hours) cannot be claimed to be 'superior' or more beneficial than prescribing or taking Prilosec 20 mg (keeping gastric pH above 4 for 11.8 hours) twice daily." *Id.* ¶ 52.
>
> • "The objective conclusion from these studies that should have been part of AstraZeneca's disclosures to doctors and the Class would have been to simply double the standard dose of Prilosec, allow generic competition, sell Prilosec over-the-counter, and forget about the 'New Purple Pill.'" *Id.* ¶ 77.

The disclaimer Plaintiffs seek to impose upon AstraZeneca is barred by federal law. The FDA bars the advertising of non-approved dosages, and the FDA has not approved 40 mg of Prilosec once a day or 20 mg of Prilosec twice a day for erosive esophagitis. Instead, "the standard 20 mg dose of Prilosec [is] recommended for most indications." Compl. ¶ 11; *see also* Prilosec Labeling, at 25 (July 12, 2002), *available at* http://www.fda.gov/cder/foi/label/2002/19810s074lbl.pdf (last visited June 30, 2005) ("[t]he recommended adult oral dose for the treatment of patients with erosive esophagitis and accompanying symptoms due to GERD is 20 mg daily for 4 to 8 weeks") (RJN, Ex. 2). The Prilosec labeling also states that in an erosive esophagitis study reflected in the labeling, "the 40 mg dose [of Prilosec] was not superior to the 20 mg dose of PRILOSEC in the percentage healing rates." *Id.* at 12-13. Thus, in seeking a judgment that Delaware law requires AstraZeneca to advise physicians to "simply double the standard dose of Prilosec [to 40 mg]" or give "Prilosec 20 mg . . . twice daily," Plaintiffs are seeking to require AstraZeneca to make a statement about the use of Prilosec that the FDA prohibits.

The Seventh Circuit's decision in *Bober*, 246 F.3d at 940-43, illustrates this point. The Court affirmed the dismissal of a consumer class action for failure to state a claim of deceptive

practices under the Illinois consumer fraud act. *Id.* at 938-43. The complaint challenged the company's failure to disclose that taking two doses of Zantac 75 (available over the counter) was equally effective, but far less expensive, than taking one dose of Zantac 150 (available only by prescription). There (unlike here) the "active ingredient" actually was the same in both medications, so the argument for a "double dose" disclosure had superficial appeal. *Id.* at 937, 941. Nevertheless, because federal law treated Zantac 75 as a separate medication from Zantac 150, with separate indications and different approved dosages, the Court held that federal law barred the manufacturer from equating the two as plaintiff requested, and precluded any liability under state law for deceptive advertising. *Id.* at 941-43.[14] Here, where the drugs in question are concededly different compounds (*see* Compl. ¶¶ 9, 38, 39, 46, 71, 72) subject to different NDAs, with different approved labeling and dosages, and variations in indications, statements regarding drug interactions, and other differences, the rule in *Bober* applies with considerably greater force.

The FDA's bar on promotion of "off-label" unapproved dosages stems in part from 21 C.F.R. § 202.1, which prohibits a prescription drug manufacturer from recommending or suggesting in advertising "any use that is not in the labeling accepted in such approved new-drug application or supplement." 21 C.F.R. § 202.1 (e)(4)(i)(a).[15] Such "off-label" advertising is recognized to include recommending or suggesting any use that deviates from the FDA-approved labeling, including "treating the indicated condition but varying the dosing regimen."

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[14] *See also Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 11 (Cal. 2004) (concluding state-law claim was preempted where the disclosure plaintiff sought conflicted with the FDA-approved warning).

[15] Congress and the FDA have established detailed regulations governing the labeling of prescription drugs and those regulations define the scope of representations that may or may not be made by a prescription drug manufacturer. Under the FDCA and applicable FDA regulations, a prescription drug's labeling must be approved by the FDA before the drug can be sold. *See* 21 U.S.C. §§ 352, 355; 21 C.F.R. §§ 314.105(c), 314.50(c)(2)(i); (continued . . .)

Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51, 55 (D.D.C. 1998), *vacated in part on other grounds*, 202 F.3d 331 (D.C. Cir. 2000); *see also* 21 U.S.C. § 352(n); *cf. Bober*, 246 F.3d at 942 (federal law precludes manufacturer from "recommend[ing] or even suggest[ing]" an '"off-label"' use). The FDA has repeatedly issued pre-enforcement warning letters to companies that refer to off-label dosages in their advertising.[16]

The FDA's bar on advertising of off-label dosages also flows from the FDA's treatment of dose-selection as central to the approval of a new drug. A company's NDA must include proposed labeling with a proposed dose for each indication. 21 C.F.R. § 314.50(a)(1). The FDA will reject the NDA if it does not include substantial evidence demonstrating that the drug is safe and effective under the conditions, including at the dosage, prescribed, recommended, or suggested in the labeling. 21 U.S.C. § 355; *see also* 21 U.S.C. § 352(f)(1), 21 C.F.R. §§ 201.100(d), 314.105(c), 314.125(b)(5). To provide substantial evidence, the NDA will include data from clinical investigations, including clinical studies conducted to determine "the side effects associated with increasing doses." 21 C.F.R. § 312.21(a)(1). The fact that the FDA

(. . . continued)

see also 21 C.F.R. § 201.57.

[16] *See, e.g.*, Letter from Lisa L. Stockbridge, Regulatory Review Officer, DDMAC, to Vincent DeStefano, Associate Director of Regulatory Affairs, Novartis, at 1 (Dec. 3, 2002), *available at* http://www.fda.gov/cder/warn/2002/10972.pdf (last visited June 30, 2005) ("Your journal advertisement is misleading because it promotes an unapproved dosing regimen for Transderm Scop."); *id.* ("FDA's determination of the appropriate dosing and dosage regimen for an indicated use of a drug is often based on a complex balance of factors related to the efficacy of the product, adverse event and toxicity risks, and considerations of administration."); Letter from Thomas W. Abrams, Director, DDMAC, to Fred Hassan, President and CEO, Pharmacia Corp., at 5 (Feb. 1, 2001), *available at* http://www.fda.gov/cder/warn/2001/DD8432.pdf (last visited June 30, 2005) ("You also promote an unapproved dosing regimen for Celebrex. . . . The approved dosing regimen for Celebrex for RA however, is 100 to 200 mg twice daily. Therefore, your suggestion that Celebrex can be safely dosed at 800 mg per day (double the approved dose) promotes an unapproved dosing regimen and is misleading.").

has approved one dose for an indication does not mean that the FDA has approved any other dose for that indication. The FDA will consider a drug "new" by reason of the "newness of a dosage . . . even though such drug when used in other dosage . . . is not a new drug." 21 C.F.R. § 310.3(h)(5). Thus, if AstraZeneca (or a manufacturer of generic omeprazole) wished to advertise that double the standard dose of Prilosec (or omeprazole) would be equally effective for erosive esophagitis as one dose of 40 mg of Nexium, the FDA would first require approval of an NDA for a 40 mg dose, or a 20-mg-twice-a-day dose, of Prilosec for erosive esophagitis.

Similarly, federal law also bars AstraZeneca from stating, either explicitly or implicitly, that Prilosec and Nexium are "the same basic drug with the same clinical benefits." Compl. ¶ 127; *see also id.* ¶¶ 14, 106, 121, 155(b). The FDA's approval of a new drug application for Nexium conclusively establishes that it is not the same product as any separately approved PPI. *See* 21 U.S.C. § 355(a) (new drug approval required for any "new" drug); 21 C.F.R. § 310.3(h) (describing "new" drugs). Any suggestion otherwise would be false or misleading and would render Nexium "misbranded" under federal law. 21 U.S.C. §§ 331(a), 352(n); 21 C.F.R. § 202.1(e)(5). Plaintiffs concede that Nexium and omeprazole have different chemical makeups (Compl. ¶¶ 9, 46, 71), and that each was subject to a separate FDA approval proceeding. *See id.* ¶¶ 2, 4-6, 32, 40. A separate NDA also was required for over-the-counter Prilosec, which is approved only for more limited indications. Prilosec OTC Labeling, at 22 (June 16, 2003), *available at* http://www.fda.gov/cder/foi/nda/2003/21-229_Prilosec_prntlbl.pdf (last visited June 30, 2005) (RJN, Ex. 3); *cf. Bober*, 246 F.3d at 941-43.

Here, as in *Bober*, Plaintiffs are seeking to compel disclosures that manufacturers are barred from making under federal law. Plaintiffs' claims are therefore preempted. *See Buckman*, 531 U.S. at 349, 353; *Geier*, 529 U.S. at 873.

C. Plaintiffs May Not Collaterally Attack The FDA's Approval Of Nexium

Because Plaintiffs may not invoke state law to compel the disclosures they seek, their Complaint reduces to the argument that Nexium should never have been marketed at all. They contend that the clinical studies that supported the NDA were "skewed" and "slanted," that an "objective conclusion" to draw from AstraZeneca's studies was to "forget about" Nexium, and that Nexium's sales are attributable only to a massive DTC advertising campaign and promotion to physicians. They conclude that "the injury to the Class could have been avoided by . . . not marketing Nexium." Compl. ¶ 163.

This broad attack also is preempted. First, the FDCA preempts any challenge to the FDA's approval of Nexium as based on studies that are "skewed" or "slanted." See *id*. ¶¶ 11, 75, 135. These are claims of "fraud on the FDA," and the Supreme Court has squarely held that the FDCA preempts such claims. *See Buckman*, 531 U.S. at 348-50, 353.

In particular, federal law flatly precludes Plaintiffs from litigating whether it was reasonable for the FDA to approve a 40 mg dose of Nexium, or whether the studies comparing a 20 mg dose of Prilosec with a 40 mg dose of Nexium were "unfair comparisons." Compl. ¶ 104; *see id.* ¶¶ 11, 50-58, 72-74, 75-80, 155(e). Such decisions are committed by Congress exclusively to the discretion of the FDA. The FDA's decision to approve a drug based on a clinical study, and to include the study results in the labeling, reflects a determination by the FDA that (1) the study was "adequate and well-controlled;" and (2) the information in the labeling is not false or misleading. *See* 21 C.F.R. § 314.125(b)(6); *see also supra*; *Healthpoint Ltd. v. Ethex, Corp.*, 273 F. Supp. 2d 817, 842 (W.D. Tex. 2001) (whether plaintiff's tests were sufficient to show safety and efficacy "are issues which are committed to the FDA").

Plaintiffs also may not challenge AstraZeneca's studies or advertising based on the statements of an "FDA reviewer." For example, Plaintiffs quote an "FDA reviewer" as stating:

"'For this indication, as with the previous two, there is no benefit when increasing the H [Nexium] dose from 20 to 40 mg. Thus the recommended dose of Nexium is 20 mg once-a-day.'" Compl. ¶ 79. An "FDA reviewer," however, does not issue the final word on approved dosages; the FDA does. As Plaintiffs elsewhere concede, the labeling confirms that the FDA ultimately approved a 40 mg dose of Nexium for healing erosive esophagitis. *See id.* ¶ 80; Nexium Labeling, at 37 (RJN, Ex. 1). As a matter of law, concerns about the efficacy of a 40 mg dose necessarily were "resolved to the FDA's satisfaction." *Pfizer, Inc. v. Mile*s, Inc., 868 F. Supp. 437, 457-59 (D. Conn. 1994) (holding that it is improper to use an FDA reviewer's notes to suggest that the drug "is somehow deficient" because the FDA ultimately approved the drug as safe and effective, and the reviewer's comments thus "do not constitute the end of the FDA's findings" regarding the drug). By reciting statements attributed to the "FDA Reviewer," Plaintiffs effectively concede that the FDA heard – and rejected – their claims; far from justifying a collateral attack on the FDA's approval, they are simply one more reason why that collateral attack is preempted.

Plaintiffs also may not challenge AstraZeneca's decision to market Nexium through the use of DTC advertising (*e.g.*, Compl. ¶ 99,) or through promotion to physicians, such as through free samples. *See id.* ¶¶ 82, 86, 88, 104, 155(m).[17] That challenge is preempted by the FDA's

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[17] Plaintiffs' other allegations regarding AstraZeneca's pricing of Nexium "in order to establish brand loyalty," Compl. ¶ 155(l), also do not state a claim. There is nothing remotely deceptive or fraudulent about offering free samples, coupons, or other discounts to encourage the purchase of a new product. "Cutting prices in order to increase business often is the very essence of competition." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). To punish such pricing would "chill the very conduct the antitrust laws are designed to protect." *Id.* Plaintiffs also do not state a claim for predatory pricing because they have not alleged that AstraZeneca priced Nexium below its costs. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222-25 (1993); *see also Advo, Inc. v. Philadelphia Newspapers, Inc.*, 51 F.3d 1191, 1198 (continued . . .)

decision to permit such advertising. *See, e.g.*, 21 C.F.R. § 202.1; *Geier*, 529 U.S. at 872, 875; *Lawrence County*, 469 U.S. at 260-61. Congress has granted the FDA authority to regulate the marketing of and promotional materials for approved drugs. 21 U.S.C. § 352(n); *see also id.* §§ 321(n), 331(a), 352(a), 353(c), (d)). Since 1985, the FDA has permitted drug manufacturers to promote prescription drugs to physicians and to consumers.[18] Any challenge under state law to DTC advertising per se, or to the promotion of prescription drugs to physicians per se, is preempted because it would directly conflict with federal law, which permits such marketing. *See* 21 U.S.C. § 352(n); 21 C.F.R. §§ 202.1, 203.1 *et seq.*; *Lawrence County*, 469 U.S. at 260-61. Those who disagree may petition the FDA for a new rule. *See* 21 C.F.R. § 10.25. They may not mount a collateral attack.

What federal law does not preempt, of course, is a straightforward claim that particular statements in a particular advertisement are not supported by FDA-approved labeling and are false or misleading. But Plaintiffs do not advance that claim here. To Plaintiffs, every ad for Nexium is inherently false and misleading, because none makes the "disclosures" Plaintiffs seek. Congress and the FDA have set the rules for new drug approval, however, and neither restricts the approval of new drugs to those that have been shown to be cost-effective as compared to other drugs, or have been tested against unapproved doses of other drugs. *Cf.* Compl. ¶¶ 10, 48, 62 (admitting that standard of efficacy is compared to placebo). To impose the disclosure requirements Plaintiffs demand would superimpose new state-law requirements for marketing a drug. Federal law preempts any such new state standards.

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(3d Cir. 1995).

[18] *See* 60 Fed. Reg. 42,581, 42,581-82 (Aug. 16, 1995) (discussing history of DTC advertising); 21 C.F.R. § 202.1; *see also* 21 U.S.C. § 353(c), (d) (regulating the use of (continued . . .)

For all these reasons, Plaintiffs' attack on AstraZeneca's decisions to seek approval for and to market a 40 mg dose of Nexium is preempted. The Complaint is thus fatally defective, and should be dismissed with prejudice.

II. PLAINTIFFS' CLAIMS ARE BARRED BY THE FIRST AMENDMENT

Plaintiffs claims are also barred by the First Amendment. Specifically, (1) Plaintiffs' challenge to AstraZeneca's successful decision to seek approval for and to market Nexium is absolutely protected under the *Noerr-Pennington* doctrine; (2) the restrictions that Plaintiffs' seek to have this Court impose on AstraZeneca's advertising constitute an impermissible burden on commercial speech; and (3) the disclosures that Plaintiffs' seek to have this Court require in AstraZeneca's advertising constitute impermissible government-compelled speech.

A. AstraZeneca's Conduct Is Protected By The *Noerr-Pennington* Doctrine

Even if Plaintiffs' challenge to AstraZeneca's conduct in obtaining approval for Nexium were not preempted under *Buckman*, it is specifically and absolutely protected by the *Noerr-Pennington* doctrine. *See Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 139 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965).[19] The FDA's approval of Nexium, including the 40 mg dose and the Nexium labeling, bars any claim that AstraZeneca's decision to seek such approval was a "sham" or otherwise actionable as part of any unlawful "scheme." *See Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 61 (1993); *Nobelpharma AB v. Implant Innovations, Inc.*, 141

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drug samples to promote prescription drugs).

[19] *See also In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 359 n.3 (D. Mass. 2004) (the *Noerr-Pennington* doctrine protects petitioning the FDA); *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 135 (E.D.N.Y. 2003) (same); *In re Warfarin Sodium Antitrust Litig.*, 1998 WL 883469, at *7-8 (D. Del. 1998), *rev'd in part on other*
(continued . . .)

F.3d 1059, 1068 n.5 (Fed. Cir. 1998); *Warfarin I*, 1998 WL 883469, at *8. For this independent reason, Plaintiffs may not use the courts to litigate the validity of the studies that AstraZeneca submitted to the FDA, or the legitimacy of marketing that is supported by the 40 mg Nexium dose that the FDA approved for treating erosive esophagitis.[20]

B. Plaintiffs' Claims Constitute An Impermissible Burden On AstraZeneca's Protected Commercial Speech

Plaintiffs are also barred by the First Amendment from using state law to impose restrictions on speech that, on its face, is not alleged to contain misstatements of fact, but is merely alleged to mislead by implication. While States may impose restrictions on commercial speech that is false or "inherently misleading," States may not impose restrictions on speech that only is "potentially misleading" by implication unless they can meet the demands either of strict scrutiny, *see Pacific Gas & Elec. Co. v. Public Util. Comm'n*, 475 U.S. 1, 8 (1986) (plurality), or at the very least, of intermediate scrutiny, *see Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). *See Peel v. Attorney Registration & Disciplinary Comm'n of Illinois*, 496 U.S. 91, 100 (1990).

Whether particular speech is false or "inherently misleading" is "a question of law." *Peel*, 496 U.S. at 108. Although States have latitude to restrict false or "inherently misleading" commercial speech, States may not define what is false or "inherently misleading" so broadly as to give any State unfettered discretion to edit commercial speech. *See, e.g., Bioganic Safety Brands v. Ament*, 174 F. Supp. 2d 1168, 1180 (D. Colo. 2001) ("Whether speech is 'inherently

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grounds, 214 F.3d 395 (3d Cir. 2000) ("*Warfarin I*") (same).

[20] *Noerr-Pennington* also bars Plaintiffs' challenge to AstraZeneca's (successful) defense of its Prilosec patents against manufacturers of generic omeprazole. *See Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221, 224 (S.D.N.Y. 2002).

misleading,' however, is a determination for the court, not the legislature, to make. If a legislature could place speech outside of First Amendment protection by simply declaring the speech 'inherently misleading,' the First Amendment . . . would be subject to de facto modification by state legislatures. Clearly, this would violate the Supremacy Clause.").

As a matter of law, AstraZeneca's advertisements are not "inherently misleading" for two reasons. First, advertisements that are alleged to imply a message by omitting certain facts are not "inherently misleading." *See, e.g.*, *Western States Med. Ctr. v. Shalala*, 69 F. Supp. 2d 1288, 1299-300 (D. Nev. 1999) (rejecting argument that advertisements at issue were "inherently misleading" because they "'imply,' by omitting certain facts, that compounded drugs have obtained FDA approval"), *aff'd in part, rev'd in part*, 238 F.3d 1090 (9th Cir. 2001), *aff'd sub nom. Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002); *Texans Against Censorship, Inc. v. State Bar of Texas*, 888 F. Supp. 1328, 1361 (E.D. Tex. 1995) (holding that state law prohibiting statements that "imply[]" approval by the State Bar violated First Amendment). Second, AstraZeneca's advertisements cannot be "inherently misleading" because, as noted above, the Complaint points to no way in which AstraZeneca's advertising is inconsistent with its federally-approved labeling. *See*, *e.g.*, *Bioganic Safety Brands*, 174 F. Supp. 2d at 1180-82 (holding "[a]s a matter of law" that statements contained in product's advertisements and EPA-approved label were "not inherently misleading"); *cf. Cytyc Corp.*, 12 F. Supp. 2d at 301. For each of these reasons, AstraZeneca's challenged advertisements are protected commercial speech because, as a matter of law, they are not "inherently misleading."

Because AstraZeneca's advertisements are not false or inherently misleading, the restrictions on such advertisements that Plaintiffs' seek to have this Court impose must pass strict scrutiny, or at the very least, intermediate scrutiny. Plaintiffs' proposed restrictions cannot

withstand such scrutiny. The Complaint contains no allegations that would demonstrate that the State has a compelling or even a substantial interest in blocking AstraZeneca from advertising Nexium or in requiring a disclaimer about the cost-effectiveness of Nexium versus Prilosec in every Nexium advertisement, or that such restrictions are the least restrictive means for the State to accomplish its goals. *See, e.g.*, *Central Hudson*, 447 U.S. at 566.

In *Peel*, for example, the Supreme Court rejected an attempt to restrict attorney advertising that was "not actually misleading" based on a "possibility of misleading some consumers." *Peel*, 496 U.S. at 106-09. The Court held that: "Even if we assume that petitioner's letterhead may be potentially misleading to some consumers, that potential does not satisfy the State's heavy burden of justifying a categorical prohibition against the dissemination of accurate factual information to the public." *Id.* at 109. Here, as in *Peel*, the possibility that advertisements implicitly could mislead some consumers about the relative merits of Nexium and Prilosec would not justify the restrictions that Plaintiffs seek to have this Court impose. *See also Thompson*, 535 U.S. at 374 ("Even if the Government had argued that the . . . speech-related restrictions were motivated by a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway, that fear would fail to justify the restrictions.").

C. Plaintiffs' Claims Constitute Impermissible Government-Compelled Speech

The Supreme Court has also made it clear that, even if Plaintiffs could persuade a court or jury that it is in the public interest to disseminate a particular message, such as information about the relative cost and efficacy of competing products, a State may not compel a private party to promote such a message as a cost of engaging in non-misleading commercial speech. *See United States v. United Foods, Inc.*, 533 U.S. 405, 410 (2001); *Thompson*, 535 U.S. at 374

(invalidating speech restrictions imposed "in order to prevent members of the public from making bad decisions with the information").

"Just as the First Amendment may prevent the government from prohibiting speech, the Amendment may prevent the government from compelling individuals to express certain views." *United Foods*, 533 U.S. at 410; *see also Johanns v. Livestock Mktg. Ass'n*, -- U.S. --, 125 S. Ct. 2055, 2064 n.7 (2005) (distinguishing permissible privately-funded government speech from impermissible government-compelled private speech); *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 71-72 (2d Cir. 1996) (compelled speech '"contravene[s] core First Amendment values'" no less than a prohibition on speech) (quoting *Paulsen v. County of Nassau*, 925 F.2d 65, 68 (2d Cir. 1991)). The First Amendment not only protects commercial speech for the benefit of consumers; it also protects the interests of commercial entities in communicating whatever truthful, nonmisleading information they wish to communicate. *See Pacific Gas & Elec.*, 475 U.S. at 15 (plurality). "For corporations as for individuals, the choice to speak includes within it the choice of what not to say." *Id.* at 16. The State thus "can assess liability for specific instances of deliberate deception, but it cannot impose a prophylactic rule requiring disclosure even where misleading statements are not made." *Riley v. National Federation of the Blind of North Carolina, Inc.*, 487 U.S. 781, 803 (1988) (Scalia, J., concurring in part and concurring in the judgment).

Plaintiffs' proposed disclosure requirement, if imposed by state law, would constitute impermissible compelled speech. If the State thinks that an off-label dosing regimen of Prilosec is more effective or cheaper than an approved dose of Nexium or that other cost-benefit information is important for physicians, patients, or insurers to have, the State may communicate that message, either directly to consumers, physicians, and third-party payors, or indirectly

through its own purchasing decisions. The State may not, however, compel AstraZeneca to carry that message as the price of advertising that is otherwise consistent with the FDA-approved labeling for an FDA-approved drug. *See Central Hudson*, 447 U.S. at 566; *Thompson*, 535 U.S. at 374; *cf. Washington Legal Foundation*, 13 F. Supp. 2d at 71 ("[W]hether compelling manufacturers to get new uses [of prescription drugs] on-label is wise government policy when considered against the backdrop of present day medical realities, financial constraints and procedural burdens is a policy question that must be addressed to Congress, not to this court.").

III. PLAINTIFFS LACK STANDING UNDER ARTICLE III AND STATE LAW AND FAIL TO SATISFY THE REQUIREMENTS OF RULE 9(b)

Every federal plaintiff must satisfy the "irreducible constitutional minimum" of standing by demonstrating that he has suffered an injury-in-fact that is (1) "concrete"; (2) "fairly trace[able]" to the conduct of the defendant; and (3) likely to be redressed by a favorable decision. *Interfaith Cmty. Org. v. Honeywell Int'l, Inc.*, 399 F.3d 248, 254-55 (3d Cir. 2005) (internal quotations and citations omitted); *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Plaintiffs also must plead the essential elements of injury and causation to maintain claims under state law, and must satisfy Fed. R. Civ. P. 9(b).[21]

It is well settled that "[t]he litigant must clearly and specifically set forth facts sufficient to satisfy the[] Art. III standing requirements." *Hospital Council of Western Pennsylvania v. City of Pittsburgh*, 949 F.2d 83, 86-87 (3d Cir. 1991); *see also Dover Historical Soc'y*, 838 A.2d

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[21] Delaware has adopted the same requirements for standing as the federal courts. *See Dover Historical Soc'y v. City of Dover Planning Comm'n*, 838 A.2d 1103, 1110-11 (Del. 2003); *Oceanport Indus., Inc. v. Wilmington Stevedores, Inc.*, 636 A.2d 892, 904 (Del. 1994); *Murphy v. United Servs. Auto Assn.*, 2005 WL 1249374, at *2 (Del. Super. Ct. May 10, 2005).

at 1109-10 ("The party invoking the jurisdiction of a court bears the burden of establishing the elements of standing"). None of the Plaintiffs satisfies these requirements.

A. Individual Plaintiffs Fail To Allege Injury-In-Fact And Causation

Each Individual Plaintiff alleges in a simple sentence only that he or she purchased Nexium and was therefore injured. Plaintiff Macken alleges that "he purchased Nexium for his own consumption and was injured as a result of Defendants' conduct." Compl. ¶ 19. Plaintiff Scofield alleges she "took Nexium until the summer of 2004 and by virtue of making co-payments for Nexium was injured." *Id.* ¶ 20. Plaintiff McGrorty alleges she "has taken Nexium since 2002 and by virtue of making co-payments for Nexium was injured." *Id.* ¶ 21. Plaintiff Tikkuri alleges he "has taken Nexium since 2004 and by virtue of making co-payments for Nexium was injured." *Id.* ¶ 22. None alleges the amount of his or her purchases, whether he or she received free samples or rebates, or whether the prices he or she paid were more or less than the other PPI he or she would have purchased. Thus, none alleges the essential elements of economic loss. *See City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 263 n.13 (3d Cir. 1998) (holding that court "need not accept as true 'unsupported conclusions and unwarranted inferences'" in ruling on a motion to dismiss) (citation omitted).

The general allegations of the Complaint do not overcome this defect. First, the Complaint alleges generally that AstraZeneca's advertising "create[d] [a] demand for Nexium where no such demand would have existed if AstraZeneca had told the truth about Nexium, and a further effect was to increase the price of Nexium beyond its worth if the truth had been told." Compl. ¶ 135; *see also id.* ¶¶ 137, 139, 141, 143, 145, 155(a). That is inherently too speculative a theory of loss to establish injury-in-fact as a matter of law. *See, e.g., Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 177 (D.D.C. 2003) (dismissing plaintiff's theory that defendant's allegedly false advertising of prescription drug could cause "price inflation");

Heindel v. Pfizer Inc., 2004 WL 1398024, at *4 (D.N.J. 2004) (same); *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 178 (N.J. Super. 2003) (same). Even if the Court accepts those general allegations as true, there are no allegations as to how any such allegedly inflated price altered the price or co-payments that these Plaintiffs actually paid.

Second, the other allegations in the Complaint do not support a finding that the purchase of Nexium is, in itself, an injury. The Complaint does not allege that Nexium is ineffective or injurious to health. In comparable instances, courts have granted motions to dismiss for failure to allege injury. *See Williams*, 297 F. Supp. 2d at 175-78 (dismissing complaint that defendants deceptively advertised a drug, thereby inflating its price, but not that the product failed to perform as advertised for them individually); *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319-20 (5th Cir. 2002) (class certification reversed and complaint dismissed where plaintiffs sought economic damages following company's withdrawal of drug from market, but did not allege that plaintiffs themselves suffered harmful side effects from the drug).

The Individual Plaintiffs have also failed to plead causation, *i.e.*, that any injury they incurred was caused by the challenged advertising. *Interfaith Cmty.*, 399 F.3d at 255 (requiring "'a causal connection between the injury and the conduct complained of ….'") (quoting *McConnell v. Fed. Election Comm'n*, 540 U.S. 93, 225 (2003)); *Stephenson v. Capano Devel.*, 462 A.2d 1069, 1077-78 (Del. 1983).[22] This is an independent reason for dismissal.

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[22] *See also* 6 *Del. C.* § 2525; *Total Care Physicians v. O'Hara*, 798 A.2d 1043, 1056 (Del. Super. Ct. 2001) (quoting *Jackson Nat'l Life Ins. Co. v. Kennedy*, 741 A.2d 377, 393 (Del. Ch. 1999)) (unjust enrichment requires "'a relation between the enrichment and the impoverishment'"); *Outdoor Technologies, Inc. v. Allfirst Fin., Inc.*, 2001 WL 541472, at * 5 (Del. Super. Ct. April 12, 2001) (negligent misrepresentation requires "justifiable reliance") (citations omitted).

First, even assuming Individual Plaintiffs paid an inflated price for Nexium, the Complaint lacks any allegations that AstraZeneca's allegedly false or misleading advertising for Nexium caused any Individual Plaintiff to make that purchase. No plaintiff alleges that he or she seeing or hearing any advertisements for Nexium (let alone ones, or when or where), or that the ads caused them to pressure their doctor to prescribe Nexium. *Cf.* Compl. ¶ 99. Those are fatal omissions. A plaintiff who has not seen, or been deceived by, an advertisement has no standing to challenge it as false advertising. *Williams*, 297 F. Supp. 2d at 177 (plaintiffs who alleged that defendants had engaged in false advertising but did not plead that they "were in any way deceived—or even saw—any of that advertising" lacked standing).

Second, no Individual Plaintiff alleges that his or her physician saw AstraZeneca's advertising for Nexium. Their doctors may have chosen to prescribe Nexium to them in the individual exercise of their independent, professional judgment; indeed, it is their duty to do so. *Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1355 (3d Cir. 1992) (physician must "exercise[] 'individual medical judgment bottomed on a knowledge of both patient and palliative'") (citation omitted); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1989) ("It is [a physician's] duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product."). For this reason as well, Individual Plaintiffs have failed to plead causation as to any prescription for Nexium that they received. *See, e.g., New Jersey Citizen Action*, 842 A.2d at 178 (dismissing complaint regarding false advertising of prescription drug where plaintiffs did not allege that they or their doctors saw or were deceived by defendant's advertising); *Rivera*, 283 F.3d at 321 (complaint dismissed because independent medical judgment of plaintiffs' physicians in prescribing medication

prevented plaintiffs' from demonstrating required causation between manufacturer's allegedly false statements about drug's safety and plaintiffs' purchase of the drug).[23]

B. Third Party Payor Plaintiffs Fail To Allege Standing

The Third Party Payor Plaintiffs have likewise failed to plead standing here. None has pleaded causation, *i.e.*, that they paid for Nexium for their members because of Defendants' allegedly false advertising.

The Third Party Payor Plaintiffs allege only that they "paid for some or all of the purchase price of Nexium prescribed to one or more of its participants or beneficiaries, and ha[ve] thereby been injured." Compl. ¶ 16 (PEBTF); *see also id.* ¶ 17 (Watters "paid for prescriptions of Nexium and thereby have been injured by Defendants' conduct"); *id.* ¶ 18 (AFSCME "paid for some or all of the purchase price of Nexium prescribed to one or more of its participants and has been injured by Defendants' conduct"). None links these payments to the advertising.

For example, none alleges that they (or their staff) viewed any challenged ads, or points to any payment decision they would have made differently if they had not seen those ads. None alleges that absent the misrepresentations, they would not have purchased or reimbursed for Nexium. *Id.* ¶ 149. The Complaint therefore lacks "allegations of specific fact that would support such conclusions" of causation. *In re Chrysler Corp. S'holders Litig.*, 1992 WL 181024, at *6 (Del. Ch. July 27, 1992) (citation omitted); *City of Pittsburgh*, 147 F.3d at 263 n.13.

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[23] *Cf. In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231, 256 (D. Del. 2002), *aff'd*, 391 F.3d 516 (3d Cir. 2004) ("the learned intermediary doctrine presents a barrier to proving that any deceptive representations made by defendant were the proximate cause of plaintiffs' injuries").

Nor do the allegations by the Third Party Payor Plaintiffs contain any theory of causation that would overcome the barrier that the learned intermediary doctrine presents to proof of causation. *See, e.g., New Jersey Citizen Action*, 842 A.2d at 178; *Rivera*, 283 F.3d at 321. The Complaint contains no factual allegations that, if proven, would show that but for AstraZeneca's allegedly false or misleading advertising, one or more physicians who prescribed Nexium to a patient for whom the Third Party Payor Plaintiffs paid medical benefits would not have done so.

C. Associational Plaintiffs Fail To Allege Article III Standing

The Associational Plaintiffs also lack standing. First, they allege no injury to themselves; none of these organizations claims ever to have purchased Nexium. Compl. ¶¶ 23-25. It is well-settled that a plaintiff must pursue his claims on behalf of himself and not third parties. *Pennsylvania Psychiatric Soc'y v. Green Springs Health Servs., Inc.*, 280 F.3d 278, 283 (3d Cir. 2002). "[U]nder long standing caselaw, '[a] named plaintiff cannot acquire standing to sue by bringing his action on behalf of others who suffered injury which would have afforded them standing had they been named plaintiffs . . . . Standing cannot be acquired through the backdoor of a class action.'" *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 175, 193 (D. Mass. 2003) ("*AWP*") (quoting *Allee v. Medrano*, 416 U.S. 802, 828-29 (1974)); *see also Murphy*, 2005 WL 1249374, at *2 ("'A plaintiff may not use the procedural device of a class action to boot strap himself into standing he lacks under the express terms of the substantive law'") (quoting *Weiner v. Bank of King of Prussia*, 358 F. Supp. 684, 694 (E.D. Pa. 1973)). For this reason, Associational Plaintiffs were dismissed from pharmaceutical pricing litigation currently pending in the United States District Court for the District of Massachusetts for failure to allege standing. *AWP*, 263 F. Supp. 2d at 193.

Second, they also lack "associational standing" to pursue claims as representatives of their members. *Pennsylvania Psychiatric*, 280 F.3d at 283. This limited exception applies only

when an association's members "would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 181 (2000); *Warth v. Seldin*, 422 U.S. 490, 516 (1975) (association lacked standing to sue where it failed to plead that its members suffered injury-in-fact as a result of defendant's conduct). The Associational Plaintiffs have not adequately pleaded that their members have standing to sue "in their own right." They allege only that their members have "purchased Nexium and been damaged by the unlawful conduct alleged herein." Compl. ¶ 24; *see also id.* ¶¶ 23, 25. This is inadequate for the same reasons set forth above regarding the Individual Plaintiffs.

Finally, even if the Associational Plaintiffs could plead that that their members have standing to sue "in their own right," their damages claims are barred. Where an association "alleges no monetary injury to itself, nor any assignment of the damages claims of its members," the association "has no standing to claim damages on [its members'] behalf." *Warth*, 422 U.S. at 515-16; *see also United Food & Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 544, 546 (1996) (same); *Pennsylvania Psychiatric*, 280 F.3d at 284 (same).

D. Plaintiffs Fail To Satisfy Rule 9(b)

Plaintiffs' failure to allege that they ever saw or heard any advertisements for Nexium, let alone which ads Plaintiffs saw, or when Plaintiffs saw them, also fails to meet the pleading requirements of Fed. R. Civ. P. 9(b). Plaintiffs must set forth with particularity "the circumstances constituting the fraud or mistake" that they complain caused their injury. Fed. R. Civ. P. 9(b); *see also Lum*, 361 F.3d at 223-24.[24] Having failed to plead any specifics as to

[24] Plaintiffs' Complaint is replete with allegations of "fraud" and expressly asserts a claim (continued . . .)

whether, when, and where they saw the challenged ads, or how those ads caused injury, Plaintiffs have failed to satisfy Rule 9(b).

Such failure also in turn means that Plaintiffs have failed to plead all the essential elements of their state law claims. For example, the Complaint lacks the specificity needed to determine whether any Plaintiff saw a challenged ad during the applicable three-year limitations period. *See, e.g., Pender v. DaimlerChrysler Corp.*, 2004 WL 2191030, at * 2 (Del. Super. Ct. July 30, 2004) (three-year statute of limitations applies to DCFA claims);[25] *Lum*, 361 F.3d at 225 (finding claim not pleaded with particularity where plaintiffs did not indicate date, time, or place of the alleged misrepresentations, the transactions in connection with which the misrepresentations were made, or who made the misrepresentations to whom).

The Complaint also precludes a determination of whether any allegedly misleading ads that described Nexium as "new" (*see* Compl. ¶¶ 112, 123, 124, 126, 128) occurred outside the six month window after launching a new drug in which the FDA expressly permits manufacturers to advertise a drug as "new." *See* note 13, *supra.* Similarly, Plaintiffs have failed adequately to plead that their transactions with Nexium "occur[red] in part or wholly within this State." *Goodrich v. E.F. Hutton Group, Inc.*, 542 A.2d 1200, 1202 (Del. Ch. 1988); *see also Benning v. Wit Capital Group, Inc.*, 2001 WL 38781, at *2 (Del. Super. Ct. Jan. 10, 2001) (no DCFA claim where there was "no allegation that a Delaware consumer was deceived by

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(. . . continued)

for negligent misrepresentation based on those same allegations. *E.g.*, Compl. ¶ 1 ("This is a class action . . . for unfair and deceptive trade practices and for consumer fraud in the marketing of the brand-name drug Nexium."); *id.* ¶¶ 179-84; *see also id.* ¶¶ 95, 104, 117, 121-22, 129, 135, 137, 139, 141, 143, 145, 155, 160-61, 166, 169-70.

[25] The same three-year statute of limitations governs each of Plaintiff's claims. *See* 10 *Del. C.* § 8106; *Merck & Co. v. SmithKline Beecham Pharms. Co.*, 1999 WL 669354, at *42 (Del. Ch. Aug. 5, 1999), *aff'd*, 766 A.2d 442 (Del. 2000)) (unjust enrichment); *Advocat v.* (continued . . .)

Defendants' trade practices"), *rev'd on other grounds*, 792 A.2d 188 (Del. 2001); *Jamgochian v. Prousalis*, 2000 WL 1610750, at *3 (Del. Super. Ct. Aug. 31, 2000). Allowing a DCFA claim to proceed without allegations of such Delaware connections would expand the scope of the DCFA beyond Delaware state court decisions to date. *See Benning*, 2001 WL 38781, at *2; *Goodrich*, 542 A.2d at 1203. As these examples illustrate, Plaintiffs' failure to comply with Rule 9(b) means that they have also failed to plead essential elements of their state law claims.

E. Plaintiffs' Complaint Should Be Dismissed With Prejudice

The fundamental defects of preemption, constitutional bar, and standing described above also plagued the complaints previously filed in the separate *Macken*, *PEBTF*, and *Watters* cases. Defendants raised them in their motion to dismiss the original PEBTF complaint and in opposition to parallel state complaints, and Plaintiffs have failed to cure them here. The Complaint should be dismissed with prejudice. *Anderson v. Ayling*, 396 F.3d 265, 271 (3d Cir. 2005) (dismissing complaint with prejudice where "amendment would be futile"); *In re Alpharma Inc. Sec. Litig.*, 372 F.3d 137, 153-54 (3d Cir. 2004) (dismissing complaint with prejudice where plaintiffs had previously filed complaints and amended consolidated complaint still failed to state a claim).

These continuing defects also illustrate why amendment would be futile. In the guise of alleging false advertising, Plaintiffs really seek to challenge the FDA's decision to permit AstraZeneca to market Nexium. The Court should not countenance any further pleading of that claim. Were the Court to afford Plaintiffs any further opportunity to amend, it should be limited to a pleading that raises specific allegations of injury caused by allegedly misleading advertising

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(. . . continued)

Nexus Indus., Inc., 497 F. Supp. 328, 334 (D. Del. 1980) (negligent misrepresentation).

that a plaintiff actually saw, that genuinely challenges the advertising as inconsistent with the FDA-approved Nexium labeling, and that does not depend on the preempted non-disclosure theory or have the other defects set forth above. Because that sort of pleading is fundamentally inconsistent with the clear aim of the Complaints Plaintiffs have filed to date, permitting any such amendment is likely to be futile.

CONCLUSION

For all of the foregoing reasons, Plaintiffs have failed to state any claim upon which relief can be granted, this Court lacks subject matter jurisdiction, and their Complaint should be dismissed with prejudice.

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